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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,362	02/20/2004	Shiping Wang	029714.00017	2424
79439 7590 10/01/2009 Arent Fox LLP and Cardinal Health, Inc. 1050 Connecticut Ave., N.W. Suite 400 Washington, DC 20036				
EXAMINER				
AHMED, HASAN SYED				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
10/01/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/783,362

**Applicant(s)**

WANG ET AL.

**Examiner**

HASAN S. AHMED

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-31, 33, 34, 43-46, 48 and 49 is/are pending in the application.
- 4a) Of the above claim(s) 7-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-31, 33, 34, 43-46, 48, and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of applicants' amendment, remarks, and RCE, all filed on 17 August 2009.

\* \* \* \* \*

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 17 August 2009 has been entered.

\* \* \* \* \*

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-31, 33, 34, 43-46, 48, and 49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,133,090 ("Modak") in view of U.S. Application No. 2002/0152538 ("McDevitt"), further in view of U.S. Patent No. 5,322,161 ("Shichman"), further in view of U.S. Patent No. 5,357,636 ("Dresdner").

Independent claim 27 recites a packaged antimicrobial elastomeric article comprising: an elastomeric article that is essentially free of powder and/or starch, and is coated on an outside surface with at least one antimicrobial agent; and a package enclosing said elastomeric article and comprising a desiccant for reducing the relative humidity in the vicinity of the elastomeric article to less than the ambient relative humidity; wherein the antimicrobial activity of the elastomeric article is extended compared to an unpackaged elastomeric article, and wherein the packaged elastomeric article is capable of being stored and/or transported for a period of time without significant loss of antimicrobial activity.

Independent claim 43 recites a packaged antimicrobial elastomeric article comprising: an elastomeric article that is essentially free of powder and/or starch, and is coated on an outside surface with a water-soluble antimicrobial agent; and a package system comprising a moisture-resistant barrier and a desiccant, said package system enclosing the elastomeric article; wherein the antimicrobial activity of the elastomeric article is extended compared to an unpackaged elastomeric article; and wherein the moisture-resistant barrier and desiccant of the package system reduce relative humidity and maintain the reduced relative humidity in the vicinity of the elastomeric article.

Modak teaches an elastomeric body (reading on claims 27 and 43) with a coating comprising an antiinfective agent (reading on claims 27 and 43) comprising chlorhexidine or pharmaceutically acceptable salts of chlorhexidine (reading on claims 27 and 45) and a lubricating agent (see col. 2, lines 9-20). Examples 3 and 4 provide a coating free of starch (reading on claims 27 and 43).

The coating may further comprise a quaternary ammonium halide (see col. 4, lines 12-13) such as benzalkonium chloride (reading on claims 27, 29, 34, 45, and 49) (see col. 2, line 61).

The coating may further comprise biomedically acceptable polymers, such as polyurethanes and silicones (see col. 2, lines 65-66). Modak explains that polymers are used, "to minimize the possibility of lubricating agent being released from the glove surface and to provide lubricity due to the nature of the polymeric component." (See col. 3, lines 1-4).

The disclosed glove provides, "an effective antiviral amount of antiinfective agent such that an effective antiviral amount of the antiinfective agent is released within ten minutes of being exposed to a fluid...Preferably, the inner coating will provide substantially instantaneous release of the antiinfective agent..." (See col. 3, lines 9-16).

The Modak reference differs from the instant application in that it does not provide a coating on an outside surface of an elastomeric article, as required by amended claims 27 and 43; however the coating of an antimicrobial composition on the outside surface of an elastomeric article is known in the prior art (see Dresdner, Example 1). Sterile packaging of the elastomeric gloves was also known in the prior art (see Dresdner, col. 1, line 66). Dresdner further teaches use of chlorhexidine gluconate (see col. 27, line 41) and benzalkonium chloride (see col. 28, line 58) as antiseptic agents.

The Modak reference differs from the instant application in that it does not teach a process of extending antimicrobial activity.

McDevitt teaches an elastomeric glove (*see* paragraph 0054). The disclosed glove is comprised of:

- the antimicrobial agent of instant claims 27 and 43 (*see* paragraph 0030);
- the packaging of instant claims 27 and 43 (*see* paragraph 0189); and
- the moisture-resistant barrier container (*e.g.* film foil laminate) of instant claims 33 and 48 (*see* paragraph 0189).

Neither Modak nor McDevitt teach a desiccant, however use of desiccants in metal foil packaging was known in the art at the time the instant application was filed as evinced by Shichman (*see* col. 2, lines 49-51).

The reduced humidity and extended antimicrobial activity of instant claims 27 and 43 are an inherent property of foil packaging containing desiccant.

McDevitt explains that packaging the gloves is beneficial, "...in order to preserve any additives applied to the finger glove or otherwise to maintain the finger glove in a sterile environment." *See* paragraph 0189.

The references are silent with respect to the time recited in instant claim 30 and the antimicrobial activity recited in instant claims 31 and 46. The prior art, as instantly claimed, discloses antimicrobial elastomeric articles packaged in foil containing desiccant (*see* above). Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose antimicrobial elastomeric articles packaged in foil containing desiccant, as taught by Modak in view of McDevitt, further in view of Shichman. One of ordinary skill in the art at the time the invention was made would have been motivated to use such a process because it leads to preservation of additives (such as antimicrobial agent), as explained by McDevitt.

\* \* \* \* \*

### ***Response to Arguments***

Applicants' arguments filed 17 August 2009 have been fully considered but they are not persuasive.

1. Applicants argue that Modak does not disclose an elastomeric article that is essentially free of powder and/or starch. See remarks, page 11.

Examiner respectfully submits that applicants use of the phrase "essentially free of powder and/or starch" in claims 27 and 43 means that the article is essentially free of powder and starch combined, powder alone, or starch alone. Thus, the claim explicitly provides three different combinations; if either of the three is disclosed in the prior art, the claims is properly rejected. Applicants suggest that the Office Action is intentionally misinterpreting the claim (see remarks, page 12, line 2), however the use of "and/or" in the claim can only mean that the claim is reciting the three combinations described above. In this case, Modak explicitly teaches at least one of the three combinations; Examples 3 and 4 of Modak provide a coating with no starch. As such, this teaching reads on instant claims 27 and 43, as currently presented.

2. Applicants argue that Modak specifically teaches that the lubricating agent is preferably a modified corn starch. See remarks, page 12.

The applicants' arguments are based on what the examiner believes to be a narrow interpretation of the prior art. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Modak explicitly provides embodiments of coating compositions that do not contain a modified corn starch (see Examples 3 and 4).

3. Applicants argue that the purpose of the Modak glove is to protect health care workers from exposure to pathogens while the purpose of the instantly claimed glove is to reduce cross-contamination. See remarks, page 12.

The difference in objectives does not defeat the case for obviousness because, as MPEP § 2144 states, the "reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) ...; In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) ... ."

4. Applicants argue that applicants do not use powdered elastomeric articles because powder does not permit substantially instantaneous release and also because



a powder-based antimicrobial coating would not be suitable for an outer coating. See remarks, page 14.

As explained above, the instant claims, as currently presented, do not preclude use of a powder, since claims 27 and 43 use the alternative "or" language, meaning the article may be essentially free of powder or starch. Additionally, in one embodiment, Modak adds polymers such as polyurethanes and silicones to the composition, which Modak explains, minimizes the possibility of lubricating agent being release from the glove surface (see col. 3, liens 1-4). Examiner respectfully submits that such a composition is not consistent with a powder.

5. Applicants argue that the two primary references (i.e. Modak and McDevitt) do not disclose a feature of the presently-claimed invention that is entitled to weight (i.e. an elastomeric article that is essentially free of powder and/or starch). See remarks, page 16.

As explained above, Modak reads on the instant application as currently claimed. Modak at least teaches an article free of starch, directly reading on claims 27 and 43. Further, in one embodiment, Modak teaches the use of polymers in the composition in order to minimize the release of lubricating agent from the glove surface, a feature is completely inconsistent with a powder formulation.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./  
Examiner, Art Unit 1615

/MP. WOODWARD/  
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